HENRY SCHEIN®
Henry Schein, Inc. • 135 Duryea Road • Melville, NY 11747

GENERAL BUSINESS: 516-843-5500
FAX: 516-843-5665
http://www.henryschein.com

June 27, 2000

7350 '00 JUL -3 A9:20

Docket Nos. 92N-0297 and 88N-0258
Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fisher Lane, Room 1061
Rockville, MD 20857

Dear Sir or Madam:

I am writing to you on behalf of Henry Schein, Inc. (HSI) regarding certain sections of the Prescription Drug Marketing Act final rule in so far as they apply to the wholesale distribution of prescription drugs. The provisions of the final rule go into effect on December 4, 2000. A stay is in effect until October 1, 2001 with regard to other sections of the rule. HSI is a licensed wholesale distributor of medical, dental and veterinary supplies, including prescription drugs, serving hundreds of thousands of healthcare professionals nationwide.

We believe that the goal of the PDMA is to assure that only quality pharmaceutical products are distributed in the United States and that prescription drugs are not diverted to "grey markets". However, we are concerned with the serious impact that certain requirements in the final rule will pose on the industry and ultimately the final consumer. We do not believe that it was the intent of the Federal policymakers in enacting the PDMA to create an undue burden on the distribution of pharmaceutical products. Therefore, HSI would like to submit the following comments:

Section 203.23(a) requires that a hospital, health care entity or charitable institution document the return of prescription drugs by issuing a credit memo. Section 203.23(b) states that the returning entity must forward to the manufacturer a copy of that "credit memo". We believe that the intent of Congress was to allow legitimate returns of prescription drugs and that FDA is not authorized to place burdensome requirements on returns.

Accordingly, HSI agrees that returned drugs must be maintained under proper conditions for storage, handling and shipping and that documentation reflecting the maintenance of proper conditions must be provided to the **supplier/distributor** to ensure that, if the returned drug is redistributed, it remains safe and effective for its intended use. This goal can be achieved via the written statement provided by the returning entity to the supplier/distributor to

which the drugs are returned. The provision of notice to the manufacturer when drugs are returned to a wholesale distributor, constitutes an unreasonable administrative burden for the returning entity, the distributor and the manufacturer. Moreover, it is incongruous that a product lot or control number is required on the credit memo accompanying a return and on the drug pedigree, but not otherwise required under the final rule. Furthermore, it violates the distributors right of customer confidentiality. The distributor should not be placed in a position necessitating that it reveal its customer list to the manufacturer. Certainly in the case of product recalls, a distributor is afforded the opportunity to notify its customers of an FDA or manufacturer initiated recall without the mandate to turn over such list to the manufacturer. Therefore, HSI suggests that section 203.23 be revised to disregard the requirement of notice, to the manufacturer with regard to returns of prescription drugs.

Section 203.50(a) of the final PDMA regulation establishes that before the completion of any wholesale distribution by a wholesale distributor of a prescription drug for which the seller is not an "authorized distributor of record" to another wholesale distributor or retail customer, the seller shall provide to the purchaser a statement identifying each prior sale, purchase or trade of such drug. This statement requires the tracking of the product by lot or control number by the wholesale distributor.

While HSI recognizes the need for this requirement, allegedly to avoid the diversion of pharmaceutical products, FDA needs to recognize that the tracking of products by lot or control number is not a current practice in the wholesale industry and it would mean costly and significant modifications to the majority of healthcare distributors current operations. Therefore, the FDA should be sensitive to the fact that most of the prescription drug distributors will need to implement new tracking systems and it may take a lengthy time period to achieve compliance with the new requirement. HSI recommends that section 203.50(a) be reviewed and FDA allow a period of 2 to 3 years for wholesalers to implement the necessary changes to comply with the final regulations.

Please consider these comments and re-evaluate the possible consequences of implementing the related provisions. We appreciate the opportunity to comment on this matter.

Sincerely,

Mark Bond R.Ph.
Vice President Medical Division

> **For purposes of this paragraph, the term "entity" does not include a wholesale distributor of drugs or a retail pharmacy licensed under state law. . . .**

Contrary to FDA's suggestion in the preamble to its proposed regulations (see 59 Fed. Reg. at 11845), the above-cited language of the statute as well as the legislative history leaves no doubt that Congress clearly envisioned scenarios where a health care entity could act as a legitimate wholesale distributor, and specifically designed the statute so as not to prohibit such activity. FDA offers no substantiation for its interpretation and the language of the statute, in fact, is antithetical to FDA's views.

Despite the clear language of the statute, FDA's proposed regulation maintains that a "health care entity" may not simultaneously be a "wholesale distributor." FDA based its decision to disregard the statute on information it has "learned" (but does not make part of the record) stating in a pertinent part that:

> . . . some hospitals and health care entities, including physicians, have obtained licenses as wholesale distributors in an effort to circumvent the statutory restrictions against the sale of prescription drugs by hospitals, health care entities and charitable institutions.

59 Fed Reg. 11842, 11845. Although CCBC respects FDA's motivations in attempting to prevent circumvention of the PDMA resale prohibitions, an absolute ban on entities acquiring wholesale distributor status not only goes much further than necessary to achieve that purpose, but completely ignores the explicit exemption carved out by the statute. In administering the PDMA, FDA must give effect to the unambiguously expressed intent of Congress. Chevron U.S.A., Inc. v. Natural Resources Defense Council, Inc., 467 U.S. 837 (1984); see also Estate of Cowart v. Nicklos Drilling Co., 112 S.Ct. 2589, 2594 (1992) (no deference will be granted to an agency position that is contrary to an intent of Congress expressed in unambiguous terms).

In addition to disregarding the clear language of the statute, FDA's proposed definition of a "health care entity" fails to comport with the agency's own interpretation of section 503(c)(3). As stated in the preamble to the proposed regulation:

> FDA interprets the first clause of the last sentence of section 503(c)(3) of the act to mean that the general prohibition against drug sales by hospitals, health care entities, and charitable institutions **was not intended to interfere with the operations of legitimate licensed prescription drug wholesalers and retail pharmacies.**

59 Fed. Reg. at 11845 (emphasis supplied). CCBC applauds FDA's recognition regarding the clear language of the statute and appreciates FDA's concern that section 503(c)(3) of the act:

> [N]ot open up a loophole for a hospital, health care entity, or charitable institution to avoid the statutory prohibition against drug sales simply by obtaining a wholesaler license.

Id. CCBC believes, however, that a clearly articulated enforcement policy would enable FDA to achieve its goal of preventing circumvention of the resale restrictions, without conflicting with the exemption provided under section 503(c)(3) of PDMA.

II. FDA's Proposed Definition of "Health Care Entity" Contradicts Congressional Intent.

A. Congressional Intent Behind the Sales Restriction Provisions

Among the purposes of PDMA was Congress' desire to eliminate the diversion submarket for prescription drugs that created an unfair form of competition for wholesale distributors and retailers who did not participate in diversionary tactics. Congress characterized the diversion submarket as the sale, barter or trade of drugs initially sold to hospitals and other health care entities at below wholesale prices. In support of its proposed definition of a "health care entity," FDA states in the preamble that:

> The legislative history, which addresses Congress' concern about donation to charitable institutions and institutional discounts for hospitals and health care entities, notes that some of these institutions had been sources of unfair competition and drug diversion, and explains that the statutory prohibition against the sale of drugs donated to or acquired at a reduced price by charitable institutions or purchased by hospitals or health care entities is directed at preventing unfair profits through resales of such drugs.

59 Fed. Reg. at 11845. Although FDA has interpreted Congressional intent correctly, to the extent FDA proposes an absolute prohibition on the ability to maintain "entity" and "wholesale distributor" status simultaneously, the agency ignores the clear wording of the statute and fails to adequately address the wrongdoing that requires remedy under PDMA. In doing so, FDA denies the statutorily mandated exception under section 503(c)(3) of the sales restriction provision of PDMA which expressly sanctions the simultaneous maintenance by an entity of wholesale distributor status. If given effect as currently proposed, FDA's definition of a health care entity would depart from and put aside the clear language of the statute. As a matter of law, FDA cannot do that. See Lynch v. Tilden Produce Co., 265 U.S. 315 (1924) (Internal Revenue regulation defining "adulterated b[illegible]" held invalid where definition conflicts [illegible] and the two could not be read in harmony). At most, FDA can prescribe some limits on the nature of that except[illegible] with the statute and the legislative intent of the law.

The legislative history of the PDMA makes clear that the sales restrictions were intended to eliminate fraud committed against manufacturers and unfair competition,

not to prohibit legitimate wholesale distribution by health care entities.[2] As stated by Congress:

> Section 503(c)(3) would prohibit resales of pharmaceuticals by hospitals and other health care entities or charitable organizations with certain exceptions. This provision is intended to cover resales by both for profit and nonprofit health care entities. These institutions typically receive discount prices, substantially below the average wholesale price (AWP) for pharmaceuticals, based on their status as a health care entity or charity. When hospitals or other health care entities obtain pharmaceuticals at favorable prices and then resell those drugs at a profit, they are unfairly competing with wholesalers and retailers who cannot obtain such a favorable price. Such resales defraud manufacturers, who are led to believe that the drugs are for the use of the health care entity. In any case, these resales reward the unscrupulous and penalize the otherwise honest and efficient wholesaler or retailer while fueling the diversion market.

H. Rep. No. 76, 100th Cong., 1st Sess. 12-13 (1987). FDA's proposed definition of a health care entity penalizes not only the unscrupulous but also the "otherwise honest and efficient wholesaler." Thus, as proposed, the regulation is overly broad, at odds with statutory language and intent and therefore unlawful.

In notes accompanying the PDMA, Congress included the following finding:

> The bulk resale of below wholesale priced prescription drugs by health care entities, for ultimate sale at retail, helps fuel the diversion market and is an unfair form of competition to wholesalers and retailers that must pay otherwise prevailing market prices.

21 U.S.C. § 353 (note, sec. 2 (8)). That finding is consistent with repeated references in the legislative history accompanying PDMA, clarifying that Congress' primary concern regarding the resale of pharmaceuticals arose because of abuses in the system that permitted certain entities to acquire pharmaceuticals at discount (because of their special institutional status), and then resell those drugs at a profit in unfair competition with wholesale distributors and retailers not granted preferential pricing. Indeed, in speaking before the House of Representatives on the PDMA, Representative John Dingell (D-MI) stated:

> The resale of prescription drugs by certain health care entities . . . which are economical only because many manufacturers sell much cheaply to certain institutions than to wholesale customers, provides an unfair competitive advantage to any wholesaler or retailer that can

[2]Although CCBC is obviously most concerned about the impact FDA's proposed regulation will have on blood centers, CCBC submits that the provision under PDMA section 503(c)(3) that an entity does not include a wholesale distributor or retail pharmacy, requires FDA to preserve the right of <u>any</u> entity to act as a wholesale distributor, consistent with the intent of PDMA.

> the preferentially priced goods. Moreover, the resales may well constitute fraud against the manufacturers, especially if the health care institution is allegedly purchasing the goods for its own use.

133 Cong. Rec. H3024 (May 4, 1987). By placing an absolute prohibition on the ability of a health care entity to concurrently maintain wholesale distributor status, FDA's proposed regulation fails to consider that blood centers (as well as other entities), may purchase pharmaceuticals (i.e. licensed blood products) that are not intended for their own use and that manufacturers understand the pharmaceuticals will be resold.[3] Under those circumstances, an entity may be a legitimate wholesale distributor acting in a manner that Congress in no way intended to penalize under the resale prohibitions of the PDMA and specifically exempted under section 503(c)(3). Thus, the plain meaning of section 503(c)(3) clearly shows that Congress recognized that a health care entity could be a legitimate wholesale distributor.

B. Congress Never Intended PDMA to Encompass Community Blood Centers or Licensed Blood Products

There has never been the slightest indication of any distribution abuse of the type banned under PDMA with respect to any licensed blood products, regardless of whether or not such products have been intended for transfusion. Thus, to the extent FDA's proposed definition of a health care entity prohibits blood centers from acting as wholesale distributors under all circumstances, it fails to effectuate any specified intent of Congress. Indeed, to the extent an absolute prohibition conflicts with the express exemption provided under section 503(c)(3), it directly conflicts with congressional intent.

Neither prior to consideration of PDMA, nor during the extensive Congressional investigations, was there any documented abuses that would suggest that Congress intended that blood centers be prohibited from simultaneously acting as health care entities and wholesale distributors. Moreover, Congress had no expectation that blood centers would be covered under PDMA at all. From the earliest implementation of PDMA, Representative Dingell, Chairman of the Committee and Subcommittee most directly responsible for the enactment of PDMA, sent FDA a clear message that blood products should be exempted from the requirements and restrictions of PDMA. In a September 29, 1988 letter submitted to FDA under Docket No. 88N-0258, Mr. Dingell stated:

> The inclusion of blood and blood components in the Sales Restriction Section of the Act derives not from explicit language in the statute or legislative history, but rather by virtue of the fact that FDA had previously defined such products as 503(b) drugs by regulation. [21 C.F.R. 606.3(a) and (c)]

---

[3]To the extent some blood centers purchase blood products for their own use, for example where blood centers with hemophilia treatment facilities purchase Antihemophilic Factor for their own patients, manufacturers selling to the blood centers should be aware of the situation.

> Indeed, nowhere in the two-volume record of the drug diversion investigation by the Subcommittee on Oversight and Investigations, the House or Senate hearings and reports, or the Floor debate is the marketing of blood and blood products even mentioned.

That FDA's attempt to prevent circumvention of the sales restrictions under PDMA is totally inappropriate in the context of blood center operations is obvious in light of the manner in which such entities act as wholesale distributors. Currently, with respect to the resale of licensed blood products, community blood centers operate in much the same manner as traditional wholesale distributors. Manufacturers grant them volume discounts with the understanding that such savings will be passed on to the hospitals, hemophilia treatment centers, and other facilities the blood centers supply. To the extent blood centers compete with wholesalers in the distribution of licensed blood products, no unfair competition exists. Furthermore, the regulatory controls exercised over all licensed blood products and the limited supply of blood available ensures that no widespread drug wholesale distribution network exists that would give rise to the abuses PDMA intended to correct. Under the current distribution system for licensed blood products it is illogical (as well as illegal) for FDA to prohibit blood centers from simultaneously acting as entities and wholesale distributors.[4]

III. Suggested Revision of FDA's Proposed Regulations That Retains FDA's Ability to Enforce the Law

Despite the clear statutory language of section 503(c)(3), establishing that entities may simultaneously act as health care entities and wholesale distributors or retail pharmacies, CCBC also recognizes that Congress did not intend that this exemption from the resale restrictions would create a loophole for entities participating in any form of prescription drug diversion. CCBC submits, however, that section 503(c)(3) of PDMA mandates a regulatory scheme be devised whereby a health care entity can operate as a wholesale distributor or retail pharmacy within lawful parameters. In other words, a health care entity may not become a licensed wholesale distributor as a "sham" to avoid the re-sales restriction. In order for FDA to accomplish its regulatory goals consistent with the statute, the agency must amend section 203.3(n) of its proposed regulations, defining a health care entity by deleting the following portions of the proposed language:

> . . . but does not include any retail pharmacy or wholesale distributor. A person cannot simultaneously be a "health care entity" and a retail pharmacy or wholesale distributor.

---

[4]CCBC continues to believe that no legitimate basis exists for distinguishing between transfusable blood products and all other licensed blood products for purposes of carving out an exemption from PDMA. As detailed in our November 13, 1990 comments submitted under Docket No. 88N-0258 (a copy of which is attached), CCBC would have FDA expand its proposed exemption from PDMA to all licensed blood products. CCBC reiterates that position and incorporates the arguments in its November 13, 1990 comments.

CCBC does not mean by this recommendation to suggest that FDA cannot enforce the sales restriction provisions of PDMA. Rather, CCBC encourages FDA to articulate, through the preamble to the final rule, the enforcement policy it intends to follow, consistent with the goals of the PDMA. Obviously, any health care entity found to be acting in a manner that violates the intent of the sales restriction provisions of PDMA (i.e. a "sham") remains subject to FDA's enforcement of the resale prohibitions, irrespective of whether the entity is also a state licensed wholesale distributor or retail pharmacy. Thus, FDA should clarify in the preamble to the final rule that any entity that defrauds a manufacturer by improperly obtaining below average wholesale prices on the basis that the prescription drugs purchased are for its own use, when such is not the case, and who then unfairly competes in the prescription drug resale market by selling those products received at below normal wholesale prices, will be subject to FDA enforcement of PDMA.

For purposes of refining its treatment of health care entities that are also licensed wholesaler distributors, CCBC points FDA to that part of the preamble to its proposed rule where the agency focuses on the improper transfer of prescription drugs, obtained at reduced prices by health care entities, to subsidiaries for resale. 59 Fed. Reg. 11842, 11846. In its description of that prohibited activity, FDA clearly recognizes the abuses PDMA's sale restrictions were intended to eliminate, i.e., resale of prescription drugs obtained at reduced price or through donations. In the same manner FDA intends to monitor those relationships, it can monitor the wholesale distribution activities of all health care entities. Nothing prohibits FDA from requiring health care entities licensed as wholesale distributors to maintain sufficient records detailing their purchase and sale of prescription drugs. This would be fully consistent with the way that PDMA and the FDA are regulating prescription drug samples. FDA could prohibit the resale of any prescription drugs purchased at below wholesale prices where such prices are obtained based solely on the status of the purchasing entity. Such regulatory controls would address Congress' concern regarding the deception of manufacturers, and would eliminate any unfair competition with traditional wholesalers, without arbitrarily proscribing the legitimate wholesale activities of honest and efficient health care entities.

Unfortunately, as currently presented, the preamble language might suggest that FDA should require a health care entity to convert its licensed drug wholesaler operations to a for-profit subsidiary. Not only would such an arbitrary rule fail to cure the conflict with the clear language of the statute detailed above, but it is not necessary for FDA to maintain full discretion to enforce the law. Blood centers should not have to restructure their corporate activities to meet an arbitrary requirement not contemplated by the statute. Rather, CCBC believes FDA should focus on whether a health care entity has obtained a State license to be a drug wholesale distributor as [illegible] for engaging in unfair competition. It is not the corporate status of the [illegible]ization (profit vs. non-profit or [illegible] [illegible] [illegible] distributor) but rather the fraudulent and unfair competitive conduct of the organization that should determine compliance with the sales restrictions provisions of PDMA. Neither the statute nor the legislative history mandate such an arbitrary decision. Again, FDA must focus on conduct and intent rather than corporate status. To do otherwise is an unlawful extension of the law.

CONCLUSION

FDA's proposed definition of a "health care entity" is a matter of great significance to blood centers and the hospitals and other health care entities they serve. CCBC strongly supports FDA's ability to enforce all of the provisions of PDMA and believes that the recommendations set forth in these comments preserve that ability, while conforming to the language and intent of the statute. Ultimately, CCBC hopes that FDA realizes that no basis exists in the law for precluding a health care entity from acting as an honest and efficient wholesale distributor.

Sincerely,

Wm. M. Coenen

William Coenen
President

Enc. Letter to Dockets, 11/13/90

Place Label in This Space

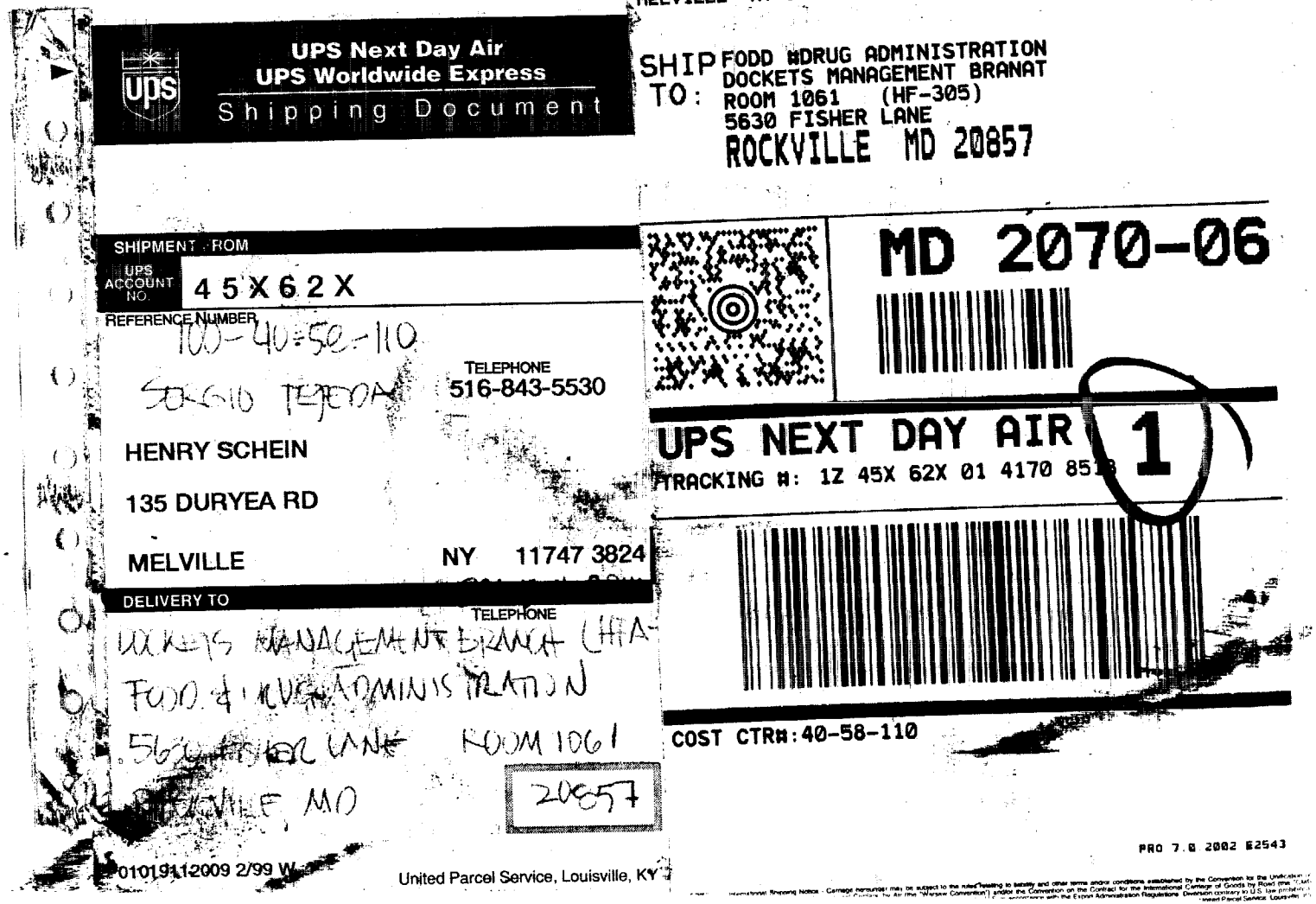
Options: UPS Tracking Label and your address label

Place the Tracking Label to the left of the address label.

Stamp your UPS Shipper Number or place parcel register tape above the address label.

UPS Air Shipping Document

UPS Waybill



UPS Next Day Air
UPS Worldwide Express
Shipping Document

HENRY SCHEIN INC.
(631)843-5530
MAILROOM
135 DURYEA RD.
MELVILLE NY 11747-3824

SHIP TO: FODD &DRUG ADMINISTRATION
DOCKETS MANAGEMENT BRANAT
ROOM 1061 (HF-305)
5630 FISHER LANE
ROCKVILLE MD 20857

MD 2070-06

SHIPMENT FROM
UPS ACCOUNT NO. 45X62X

REFERENCE NUMBER
100-40-58-110
SERGIO TEJEDA

TELEPHONE
516-843-5530

HENRY SCHEIN
135 DURYEA RD
MELVILLE NY 11747 3824

DELIVERY TO
DOCKETS MANAGEMENT BRANCH (HFA-
FOOD & DRUG ADMINISTRATION
5630 FISHER LANE ROOM 1061
ROCKVILLE MD 20857

TELEPHONE

UPS NEXT DAY AIR 1

TRACKING #: 1Z 45X 62X 01 4170 851[illegible]

COST CTR#:40-58-110

PRO 7.0 2002 E2543

0101911 2009 2/99 W

United Parcel Service, Louisville, KY